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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,295	05/17/2005	Aleksander Resman	RG/G-33025A/Lek	9703

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EXAMINER	
GEORGE, KONATA M	
ART UNIT	PAPER NUMBER
1616	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,295	RESMAN ET AL.	
	Examiner	Art Unit	
	KONATA M. GEORGE	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 17-19* is/are rejected.

7)☒ Claim(s) *11-16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/14/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-19 are pending in this application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on January 14, 2005 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Specification

The disclosure is objected to because of the following informalities: The specification lacks antecedent basis with respect to analogues. Applicant claims in claim 17 a pharmaceutical formulation with clarithromycin or analogues. However, it is not mention in the body of the specification what these analogues are or how to arrive at them.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 19 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 19 recites the phrase "The use of",

this phrase does not fall into one of the four patent eligible subject matter as recited in 35 U.S.C. 101 (process, machine, manufacture or composition of matter).

Claim 19 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The applicant claims a pharmaceutical formulation with clarithromycin or analogues thereof, however, the specification does not give any guidance to what these analogues are or how to make them.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112 first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CaAFC,1988)).

Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) that amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The nature of the invention is a pharmaceutical formulation with clarithromycin or analogues thereof wherein the substance is modified according to the method of claim 1.

(2) The state of the prior art:

The state of the prior art as it pertains to the use of clarithromycin or analogues is very low. There are very few references which teach the use of clarithromycin or analogues.

(3) The relative skill of those in the art:

The relative skill of this in the art is high, Ph.D. level technology.

(4) The predictability or unpredictability of the art:

The art pertaining to making the analogues of clarithromycin is predictable. A323348 is a well known analogue of clarithromycin.

(6) The amount of direction or guidance presented:

The specification does not provide direction or guidance with respect to how to make the analogues of clarithromycin or what the analogues of clarithromycin are.

(7) The presence or absence of working examples:

The specification does not provide any working examples with respect to how to make the analogues of clarithromycin.

(8) The quantity of experimentation necessary:

The specification did not enable any person skilled in the art to which is pertains to make analogues of clarithromycin commensurate in scope with this claim. In particular, the specification fails to enable the skill artisan to practice the invention without undue experimentation.

Based on the lack of direction, guidance and the quantity of undue experimentation, one skilled in the art could not perform the process without undue experimentation; see In re Armbruster 185, USPQ CCPA.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite because the applicant recites the word “others” when describing pharmaceutically acceptable excipients. It is unclear to the examiner what is met by “others” when referring to pharmaceutically acceptable excipients.

Claim 9 recites the limitation "in that the particles" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 9 depends from claim 1; however, there is recitation in claim 1 of the composition comprising particles.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 6, 7 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Suh et al. (US 6,515,116).

Suh et al. discloses on column 6, lines 3-26 a method that comprises a suspension of clarithromycin in a solvent mixture comprising water followed by a drying step.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 8 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collin (EP 0 415 522).

Applicants claim a method of physical pretreatment of an active substance, characterized in that is comprises adding a poor solvent **or** a mixture of solvents to the active substances **or** to a mixture of the active substance with other excipients, wherein the solubility of the substance in said solvent is less than 0.1 g/L, followed by a drying step.

Determination of the scope and content of the prior art

(MPEP §2141.01)

Collin teaches on page 2, lines 39-43 a process comprising an active agent (ondansetron hydrochloride dihydrate) and a solvent and wherein the mixture is desolvated by drying which is then rehydrated. In is the opinion of the examiner that since the composition is desolvated the mass of the active agent in the tablet will be over 30% as claimed in claims 4 and 5. Page 2, lines 46-47 teaches the particle size. Page 2, lines 9-14 teaches how ondansetron is used to treat a variety of conditions, including nausea and vomiting. Page 3, lines 10 teach that the composition will contain at least one physiologically acceptable carrier or excipient.

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

Collin does not teach the solubility of the substance in the solvent.

Finding of prima facie obviousness

***Rational and Motivation* (MPEP §2142-2143)**

It is the position of the examiner that although Collin does not explicitly cite the solubility of the substance, it is implied and would have been obvious. The process described by Collin is a wet granulation method, which comprises the use of a solvent followed by a drying step. As such, the solubility of the active substance could be determined by the skilled artisan when selecting the preferred active substance and

solvent. This determination would have been made through routine experimentation to achieve the desired results of the claimed invention. This is in the absence of any clear showing of unexpected results attributable to the specific solubility of the active substance in the solvent employed by applicant in the instant case.

Allowable Subject Matter

Claims 11-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art reference Suh et al. do not teach, suggest nor make obvious that the clarithromycin is micronized, that the clarithromycin enters a direct mixture for tabletting or that the cores are coated.

Conclusion

Claims 1-10 and 17-19 are rejected.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8:00AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached at 571-272-0646. The fax phone

numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Konata M. George/
Primary Examiner, Art Unit 1616